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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,849	10/29/2003	Jerome David	SPINE 3.0-414	7827
530 7590 02/26/2009 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER				
SWIGER III, JAMES L				
ART UNIT		PAPER NUMBER		
3775				
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02/26/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/695,849

Applicant(s)

DAVID, JEROME

Examiner

JAMES L. SWIGER

Art Unit

3775

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 39-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 39-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date 11/14/2008.
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/2008 has been entered.

Claim Objections

Claims 2-18, 23-24, 27-28 and 30 are objected to because of the following informalities: The preamble of the claims should read --bone fixation assembly-- instead of just "assembly" to make the claims clear, and the claim language consistent. Appropriate correction is required.

Claim 19 objected to because of the following informalities: It is suggested to amend "coupling member" to --coupling element-- found in lines 6 and 10, so applicant is clear that this is what is being referred to. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18, 39, 19-23, 40, 43, 29-30, 46, and 31, 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has claimed a "compressive ball ring." Applicant has discussed that a locking element can cause compression of the ball ring, and that the ball ring can be compressed. Applicant also notes that when a locking nut exerts a radial force on the ball ring, the ball ring, in turn, exerts a compressive force onto a fixation element. The definition of "compressive" (adj.) is interpreted as 'compressing; tending to compress; or having the power to compress as part of an inherent nature.' Thus applicant does not have support for a ball ring, where it has the ability to cause compression itself without the assistance of another component of the device.

Appropriate action is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18, 39, 19-23, 40, 43, 25, 41, 44, 26-28, 42, 45, 29-30 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 19, 25-26 and 29 recite the limitation "the head portion." There is insufficient antecedent basis for this limitation in the claim. Applicant has mentioned the head portion of a fixation element as only a functional limitation of the claim and it is not positively recited. Applicant appears to be referring back to positively recited structure.

Claims 8-9 recite the limitation "the locking nut." There is insufficient antecedent basis for this limitation in the claim. Applicant changed dependency of the claims and there is no antecedent basis for a locking nut.

Claims 16-17 recite the limitation "the bore" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant is referring to a first or second bore.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-18, 25-31, 39, 41-42 and 44-47 rejected under 35 U.S.C. 103(a) as being unpatentable over Studer (US Patent 6,146,383) in view of Young (US Patent 6,626,906).

Studer et al. disclose a bone fixation assembly comprising what is considered a unitary coupling element (see element in Fig. 2), that has a first bore which is adapted to receive a fixation element that has a head portion(11/1), a second bore that is transverse to the first bore (28), that is also adapted to receive a spinal rod (18). The bone fixation assembly also has a first locking element which may also be considered a nut (7) to secure the head portion in the first bore and a second locking element (24) adapted to secure the spinal rod in the second bore. The shoulder is considered to be an edge where the bore meets the interior cavity. The bone fixation assembly also

comprises a locking portion has a ball ring member (9). It is noted that the locking element can cause compression of the ball ring, where the ball ring can be considered a compressed ball ring. This locking element provides a means for exerting a compressive, radial force. The second bore shown with a spinal rod has an axis that is transverse to the first bore, extending coplanar in the transverse direction. Further, once the second locking element (through bore 29 with set screw 24) is set into the device, it is capable of being permanent if the user chooses it to be and would be fully secure in the connection and to stabilize the rod in place. The device further comprises male threads in the first bore (see Fig. 15), and where at least a portion of the locking nut surrounds the ball ring and causes compression. The male threads would inherently fit into the female threads provided on the side of the first bore (see drawing). The ball ring (9) is also in contact with the coupling member portion (5) at the bottom end of the ring, and a locking member/nut (7) at the top. The bottom portion of the ball ring (9) is tapered to allow poly-axial motion. See also Fig. 20, XXII for this tapered portion.

Studer et al. claim the invention except for a coupling element and compression element that allow a fixation element to perform not only axial movement but also linear movement. This means that the fastener can slide up and down, but may be controlled by a first locking element in combination with a compressive member for securing the head of the fastener at any point along the length of the head portion of the fastener. Young et al. disclose a connection fixation device that teaches a head portion of a fixation screw (8) that can move up and down linearly and wherein it may be fixed anywhere along this portion by the compression means (see fig. 6, and Col. 2, lines 31-

42). Young discloses a compressive member that has slits (17), that enables compression. It is further noted that Young discloses another embodiment such as a split ring (3) which may also be compressed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Studer et al. having at least the coupling element and fastener head combination to allow linear movement in view of Young et al. to have more surgical control over placement of the fixation device during surgery.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Studer in view of Young as applied to claim 5 above, and further in view of Errico et al. (US Patent 5,776,135). Studer in view of Young teach the claimed invention except for a second locking element having a flared lip helps to keep it in place. Errico et al. teach a locking element such as a set screw (158) that has a bottom portion that is considered flared. As it is placed into the bore, it is shaped to better be maintained in the space. The hourglass shape helps to hold it in place with the rest of the apparatus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Studer in view of Young having the flared lip in further view of Errico et al. to better maintain the locking element in place.

Claims 19-24, 40, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Studer (US Patent 6,146,383) in view of Young (US Patent 6,626,906). Studer in view of Young teach the claimed invention and structural elements except for wherein the invention has the structure in a pre-assembled format.

With regards to Studer in view of Young, the claimed invention appears to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Response to Arguments

Applicant's arguments with respect to claims 1-31 and 39-47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3775

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732